

fw

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450 Alexandria, VA 22313-1450, on 6/17/05

Yong Shin



PATENT

Attorney Docket No. 29914.703.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)

PATENT APPLICATION

Inventor(s): David STINSON et al.)

Art Unit: 3732

Application No.: 10/615,417)

Examiner: Kevin P. Shaver

Filed: July 8, 2003)

Confirmation No.: 7968

Title: Prostheses, tools and methods for
replacement of natural facet joints with
artificial facet joint surfaces)

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:

- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage
-- OR --
- ☒ (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:

- ☐ a certification as specified in §1.97(e) is provided below; or
- ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:

- A. a certification as specified in §1.97(e) is completed below; and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

☒ Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.), copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- ☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed.)
- ☐ There are no listed references which are not in the English language.
- ☒ The relevance of those listed references which are not in the English language is as follows: Japanese Patent Publication 10179622 A2 was published in Japanese and PCT applications WO 95/05783 A1, WO 98/48717 A1 and WO 99/23963 A1 were published in French. The English language abstracts and the drawings of each are sufficient to convey the scope of their disclosure.
Should the Examiner believe that a complete translation of any of the Japanese or French PCT publications is necessary to understand their disclosure, Applicants will endeavor to provide such translation at the Examiner's request.
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.29914.703.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 6/17/05

By: Benjamin M. Glenn

Benjamin Glenn, Reg. No. 44,713

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/615,417
Filing Date	07/08/2003
First Named Inventor	Stinson et al.
Art Unit	3732
Examiner Name	Shaver
Attorney Docket Number	29914.703.201

Sheet 1 of 4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-2004/0059429	03/25/2004	Amin et al.	
		US-3,867,728	02/25/1975	Stubstad et al.	
		US-3,875,595	04/08/1975	Froning	
		US-4,349,921	09/21/1982	Kuntz	
		US-4,759,769	07/26/1988	Hedman et al.	
		US-4,772,287	09/20/1988	Ray et al.	
		US-4,863,477	09/05/1989	Monson	
		US-4,904,260	02/27/1990	Ray et al.	
		US-4,911,718	03/27/1990	Lee et al.	
		US-5,047,055	09/10/1991	Bao et al.	
		US-5,071,437	12/10/1991	Steffee	
		US-5,147,404	09/15/1992	Downey	
		US-5,171,280	12/15/1992	Baumgartner	
		US-5,192,326	03/09/1993	Bao et al.	
		US-5,306,308	04/26/1994	Gross et al.	
		US-5,306,309	04/26/1994	Wagner et al.	
		US-5,370,697	12/06/1994	Baumgartner	
		US-5,401,269	03/28/1995	Buttner-Janz et al.	
		US-5,437,672	08/01/1995	Alleyne	
		US-5,458,642	10/17/1995	Beer et al.	
		US-5,458,643	10/17/1995	Oka et al.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known		
				Application Number	10/615,417	
				Filing Date	07/08/2003	
				First Named Inventor	Stinson et al.	
				Art Unit	3732	
				Examiner Name	Shaver	
Sheet	2	of	4	Attorney Docket Number		29914.703.201

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-5,514,180	05/07/1996	Heggeness et al.	
		US-5,534,028	07/09/1996	Bao et al.	
		US-5,534,030	07/09/1996	Navarro et al.	
		US-5,545,229	08/13/1996	Parsons et al.	
		US-5,556,431	09/17/1996	Buttner-Janz	
		US-5,571,189	11/05/1996	Kuslich	
		US-5,645,597	07/08/1997	Krapiva	
		US-5,653,762	08/05/1997	Pisharodi	
		US-5,674,295	10/07/1997	Ray et al.	
		US-5,674,296	10/07/1997	Bryan et al.	
		US-5,676,701	10/14/1997	Yuan et al.	
		US-5,683,464	11/04/1997	Wagner et al.	
		US-5,702,450	12/30/1997	Bisserie	
		US-5,716,415	02/10/1998	Steffee	
		US-5,824,093	10/20/1998	Ray et al.	
		US-5,824,094	10/20/1998	Serhan et al.	
		US-5,865,846	02/02/1999	Bryan et al.	
		US-5,868,745	02/09/1999	Alleyne	
		US-5,893,889	04/13/1999	Harrington	
		US-6,001,130	12/14/1999	Bryan et al.	
		US-6,014,588	01/11/2000	Fitz	
		US-6,019,792	02/01/2000	Cauthen	
		US-6,039,763	03/21/2000	Shelokov	
		US-6,063,121	05/16/2000	Xavier et al.	
		US-6,066,325	05/23/2000	Wallace et al.	
		US-6,080,157	06/27/2000	Cathro et al.	
		US-6,113,637	09/05/2000	Gill et al.	
		US-6,132,465	10/17/2000	Ray et al.	
		US-6,669,729	12/30/2003	Chin	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/615,417
				Filing Date	07/08/2003
				First Named Inventor	Stinson et al.
				Art Unit	3732
				Examiner Name	Shaver
Sheet	3	of	4	Attorney Docket Number	29914.703.201

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ² - Number ³ - Kind Code ⁴ (if known)				
		DE 10135771 A1	02/20/2003	Aesculap AG & Co.		X
		IE S970323	06/03/1998	Eskina Developments Limited		
		JP 10179622 A2	07/07/1998	Mizuho Ika Kogyo KK		X
		WO 95/05783 A1	03/02/1995	Fairant, Paulette		X
		WO 98/48717 A1	11/05/1998	Taylor, Jean		X
		WO 98/56301 A1	12/17/1998	Kyphon Inc.		
		WO 99/05995 A1	02/11/1999	Gordon, Maya, Roberts & Thomas Number 1 LLC		
		WO 99/23963 A1	05/20/1999	Dimso		X
		WO 99/60957 A1	12/02/1999	Nuvasive, Inc.		
		WO 99/65412 A1	12/23/1999	Pioneer Laboratories, Inc.		
		WO 00/38582 A1	07/06/2000	Nuvasive, Inc.		
		WO 00/62684 A1	10/26/2000	Nuvasive, Inc.		
		WO 01/30248 A1	05/03/2001	Reiley, Mark A.		
		WO 01/97721 A2	12/27/2001	Kyphon Inc.		
		WO 02/089712 A1	11/14/2002	Gerber, David et al.		
		WO 03/020143 A1	03/13/2003	Synthes		
		WO 03/101350 A1	12/11/2003	Archus Orthopedics Inc.		
		WO 2004/071358 A1	08/26/2004	Archus Orthopedics Inc.		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/615,417
				Filing Date	07/08/2003
				First Named Inventor	Stinson et al.
				Art Unit	3732
				Examiner Name	Shaver
Sheet	4	of	4	Attorney Docket Number	29914.703.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		GOH, JC et al., "Influence of PLIF cage size on lumbar spine stability", <i>Spine</i> , (January 2000), 25(1) Medline abstract (one page).	
		HEAD, WC, "Wagner surface replacement arthroplasty of the hip. Analysis of fourteen failures in forty-one hips", <i>J Bone Joint Surg. Am.</i> , (March 1981) 63(3), Medline abstract (one page).	
		KHOO, LT et al., "A biomechanical analysis of the effects of lumbar fusion on the adjacent vertebral motion segment", Proceedings of the 2000 Annual Meeting of the North American Spine Society, New Orleans.	
		KOTANI, Y. et al., "The effects of spinal fixation and destabilization on the biomechanical and histologic properties of spinal ligaments. An in vivo study.", <i>Spine</i> , (March 15, 1998) 23(6), Medline abstract (2 pages).	
		LEMAIRE, JP et al., "Intervertebral disc prosthesis: results and prospects for the year 2000", <i>Clinical Orthopaedics and Related Research</i> , No. 337, pp. 64-76.	
		NAGATA, H. et al., "The effects of immobilization of long segments of the spine on the adjacent and distal facet force and lumbrosacral motion", <i>Spine</i> , (December 1993), 18(16):2471-2479, (9 pages).	
		NIBU, K. et al., "Multidirectional stabilizing potential of BAK interbody spinal fusion system for anterior surgery [see comments]", <i>J Spinal Discord</i> , (August 1997), 10(4), Medline abstract (one page).	
		TSANTRIZOS, A. et al., "Segmental stability and compressive strength of posterior lumbar interbody fusion implants", <i>Spine</i> , (August 1, 2000) 25(15), Medline abstract (one page).	

Examiner signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.